

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75-036

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO.5
2. ANDA # 75-036
3. NAME AND ADDRESS OF APPLICANT
Bedford Laboratories (BL)
A division of Ben Venue laboratories, Inc. (BVL)
300 Northfield Road
Bedford, Ohio 44146
4. BASIS OF SUBMISSION
Listed drug product is Platinol^R -AQ (Cisplatin Injection) by
Bristol-Myers Squibb.
5. SUPPLEMENT(s)
N/A
6. PROPRIETARY NAME
None used
7. NONPROPRIETARY NAME
Cisplatin Injection
8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A
9. AMENDMENTS AND OTHER DATES:
FIRM:
Original submission: 12-23-96
Minor Amendment: 3-6-00
* NC: 7-24-00
* Minor Amendment: 9-29-00

FDA:
Accepted for filing: 12-24-96 (Acknowledgment letter: 2-26-97)
NA (Major) letter: 5-15-97
NA (Facsimile) letter: 9-22-98
Tentative Approval: 12-29-98
NA letter w/minor amendment: 4-4-00
10. PHARMACOLOGICAL CATEGORY
Metastatic Testicular Tumors
Metastatic Ovarian Tumors
Advanced Bladder Cancer
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)
NDA: 18-057

Whe

14. POTENCY
1 mg/mL
50 mL, 100 mL

15. CHEMICAL NAME- AND STRUCTURE
See CR # 1.

16. RECORDS AND REPORTS
N/A

17. COMMENTS

DMF - the manufacturer of Cisplatin is adequate per review conducted by this reviewer on 10-16-00.

There is no change in specifications for the Cisplatin drug Substance in USP since Tentative Approval of this ANDA and CR # 4 written on 3-29-00 prior to sending NA letter based on Withhold status of EER.

FPL: Acceptable per labeling review completed on 3-8-00.

EER has a withhold status as of 3-10-00 by B. Hartman. A FUR has been requested.

18. CONCLUSIONS AND RECOMMENDATIONS
Approved pending EER.

19. REVIEWER: DATE COMPLETED:
Mujahid L. Shaikh 10-16-00

CC :

Endorsements:

HFD-625/M. Shaikh/10/16/00
HFD-625/M. Smela/10/17/00

Mujahid Shah 10/30/22
MSMela
10/30/00

Page(s) _____

Contain Trade Secret,
Commercial/Confidential
Information and are not
releasable.

Chen Rev 5
10/30/00